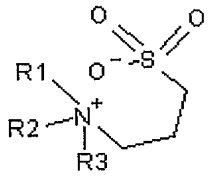
Patent claims

1. A pharmaceutical composition which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine (NDSB).
2. The pharmaceutical composition according to claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of a therapeutically effective synthetic or natural organic molecule and a therapeutically effective protein.
3. The pharmaceutical composition according to claim 2, wherein the therapeutically effective protein is selected from the group consisting of granulocyte-colony stimulating factor, interferons, interleukins, granulocyte-macrophage colony-stimulating factor, macrophage colony-stimulating factor, epidermal growth factor, erythropoietin, follicle-stimulating hormone, human serum albumin, deoxyribonuclease, fibroblast calcitonin, hematoprotein; plasminogenic activators and their precursors, cytokines; TNF family of ligands, soluble receptors, growth hormones, lipoproteins; alpha-1-antitrypsin; insulin, proinsulin, subunit A of insulin, subunit B of insulin; glucagons; blood coagulation factors, bombasine; thrombin; enkephalinase; macrophage inflammatory protein (MIP-1-alpha); relaxin A subunit, relaxin B subunit, prorelaxin; inhibin; activin; vascular endothelial growth factor; hormone receptors or growth factor receptors; integrins; protein A, protein D; rheumatoid factors; bone-derived neurotrophic factor, neurotropin-3,-4,-5, or –6; nerve growth factor, platelet-derived growth factor, fibroblast growth factor, transformed growth factor, insulin-like growth factor, thrombopoietin, bone morphogenetic protein and superoxide dismutase.
4. The pharmaceutical composition according to claim 3, wherein the therapeutically effective protein is G-CSF.
5. The pharmaceutical composition according to any of the preceding claims, wherein the NDSB is quaternary ammonium salt of Formula 1,



Formula 1

wherein R1, R2 and R3 can be the same and/or different and are selected from the group consisting of methyl, ethyl, propyl, butyl, pentyl, hexyl or their derivatives, and R4 is $(CH_2)_n$, wherein n is between 1 and 6.

6. The pharmaceutical composition according to claim 5, wherein the NDSB is selected from the group consisting of dimethylethyl-(3-sulphopropyl)-ammonium salt, 3-(1-pyridino)-1-propanesulfonate, dimethylbenzylammonium propanesulfonate, dimethyl-t-butyl-(3-sulphopropyl) ammonium salt, 3-(1-methylpiperidine)-1-propanesulfonate and dimethyl-(2-hydroxyethyl)-(sulphopropyl)-ammonium salt.
7. The pharmaceutical composition according to claim 6, wherein the NDSB is dimethyl-t-butyl-(3-sulphopropyl) ammonium salt.
8. The pharmaceutical composition according to claims 1 to 7, wherein said composition optionally further comprises a polyol.
9. The pharmaceutical composition according to claim 8, wherein the polyol is selected from the group consisting of sorbitol, glycerol, inositol, trehalose and mannitol.
10. The pharmaceutical composition according to claims 1 to 9, wherein said composition optionally further comprises one or more pharmaceutically acceptable excipients.
11. The pharmaceutical composition according to claim 10, wherein a pharmaceutically acceptable excipient is selected from the group consisting of EDTA and DMSO.
12. A process for preparation of a pharmaceutical composition, wherein said pharmaceutical composition is prepared by mixing a NDSB with therapeutically effective amount of an active pharmaceutical ingredient.
13. Use of a NDSB for the preparation of a pharmaceutical composition.

14. Use of a NDSB as a stabiliser in a pharmaceutical composition.

15. Use of a NDSB as a buffering agent in a pharmaceutical composition.

16. Use of a NDSB as a pH adjusting agent in a pharmaceutical composition.